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TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT REPELLENT--ETC(U)
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UNITED STATES ARMY ENVIRONMENTAL HYGIENE AGENCY

ABERDEEN PROVING GROUND, MD 21010

TOPICAL HAZARD EVALUATION PROGRAM
OF CANDIDATE INSECT REPELLENT AI3-70820-Ga
US DEPARTMENT OF AGRICULTURE PROPRIETARY COMPOUND
STUDY NO. 75-51-0230-80
AUGUST 1979 - JANUARY 1980

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A preliminary hazard evaluation of AI3-70820-Ga was performed by means of laboratory animal studies using rats, rabbits, and guinea pigs. The technical grade compound caused mild primary skin irritation and mild corneal irritation. It did not cause any photoirritation, did not sensitize guinea pigs, and did not prove to be an acute ingestion hazard. It was recommended that AI3-70820-Ga, US Department of Agriculture Proprietary Compound, be approved for further testing as a candidate insect repellent.

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DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

CPT Singer/lr/AUTOVON
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HSE-LT-T/WP

24 MAR 1980

SUBJECT: Topical Hazard Evaluation Program of Candidate Insect Repellent AI3-70820-Ga, US Department of Agriculture Proprietary Compound, Study No. 75-51-0230-80, August 1979 - January 1980

Executive Secretary
Armed Forces Pest Control Board
Forest Glen Section, WRAMC
Washington, DC 20012

A summary of the pertinent findings and recommendations of the inclosed report follows:

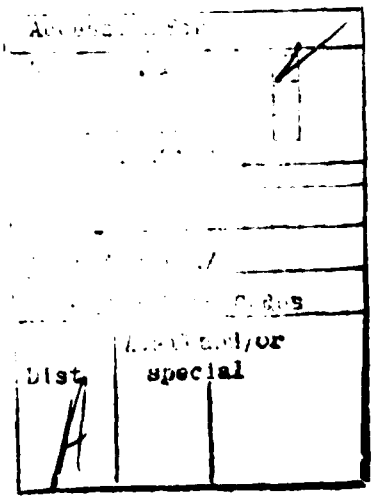
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DEPARTMENT OF THE ARMY
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TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT REPELLENT AI3-70820-Ga US DEPARTMENT OF AGRICULTURE PROPRIETARY COMPOUND STUDY NO. 75-51-0230-80 AUGUST 1979 - JANUARY 1980

1. AUTHORITY.

a. Letter, US Department of Agriculture - Agricultural Research Service, Southern Region, Insects Affecting Man and Animals Research Laboratory, Gainesville, Florida, 30 August 1979.

b. Memorandum of Understanding between the US Army Environmental Hygiene Agency; the US Army Health Services Command; the Department of the Army Office of The Surgeon General; the Armed Forces Pest Control Board; and the US Department of Agriculture, Agricultural Research, Science and Education Administrations, titled, Coordination of Biological and Toxicological Testing of Pesticides, effective 23 January 1979.

2. REFERENCE. Toxicology Division Procedural Guide, US Army Environmental Hygiene Agency (USAEHA), 1972, revised 1976.

3. PURPOSE. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellent AI3-70820-Ga.

4. SUMMARY OF FINDINGS. A hazard evaluation of the candidate repellent AI3-70820-Ga, US Department of Agriculture (USDA) Proprietary Compound, was conducted by this Agency using New Zealand White rabbits for skin and eye studies, Hartley guinea pigs for a skin sensitization study, and Sprague-Dawley rats for determination of oral toxicity. A tabular presentation of animal toxicity data developed in this Agency follows:*†

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* In conducting the studies described in this report, the investigators adhered to the "Guide for the Care and Use of Laboratory Animals," US Department of Health, Education and Welfare Publication No. (NIH) 74-23, revised 1978.
† The experiments reported herein were performed in animal facilities, fully accredited by the American Association for the Accreditation of Laboratory Animal Care.

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TABLE. PRESENTATION OF DATA

Test	Results	Interpretation
SKIN IRRITATION STUDIES		
Rabbits		
Single 24-hour application to intact and abraded skin of New Zealand White rabbits. 0.5 ml technical grade compound applied to each of six rabbits.	Compound AI3-70820-Ga caused a mild irritation to intact skin and the skin surrounding an abrasion.	USAEHA Category II (ref Appendix).
EYE IRRITATION STUDIES		
Rabbits		
Single 24-hour application of 0.1 ml technical grade compound to one eye of each of six New Zealand White rabbits.	Compound AI3-70820-Ga caused a mild corneal irritation in 6 of 6 rabbits at 24 hours. Evidence of injury was present at 48 hours, but all eyes had healed by 72 hours.	USAEHA Category C (ref Appendix).
APPROXIMATE LETHAL DOSE (ALD)		
Oral		
Rats (male) - no diluent	ALD = 6500 mg/kg	Presents little lethal hazard from accidental ingestion.

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Test	Results	Interpretation
PHOTOCHEMICAL SKIN IRRITATION STUDIES		
Rabbits		
A single 0.05 ml application of a 25-percent (w/v) solution of the compound and a 10-percent (w/v) Oil of Bergamot solution (positive control) in 95-percent ethyl alcohol were applied to the intact skin of six rabbits. Five minutes after application, the rabbits were exposed to UV light (365 nm) for 30 minutes at a distance of 10-15 cm.	A 25-percent solution of AI3-70820-Ga in ethanol did not cause a photochemical irritation reaction under test conditions. Positive control application and irradiation caused greater irritant effects than in unirradiated skin areas.	Compound AI3-70820-Ga did not cause a photochemical irritation reaction under test conditions and is not expected to cause a photochemical irritation in humans.
Control		
Following UV exposures of the rabbits, 0.05 ml of test compound, positive control and diluent were applied to additional skin areas to serve as unirradiated control sites. Application areas were checked for skin irritation at 24, 48 and 72 hours.		

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Test	Results	Interpretation
SENSITIZATION STUDIES		
Guinea Pigs (Male)		
Intradermal injections of 0.1 ml of a 0.1 percent solution (w/v) of AI3-70820-Ga or of dinitrochlorobenzene (DNCB)* in a mixture containing 1 volume of propylene glycol and 29 volumes of saline.		
Ten test guinea pigs were given 10 sensitizing doses over a 3-week period. After 2 weeks rest, they were challenged with ID injections of test compound.	Challenge dose of AI3-70820-Ga did not produce a sensitization reaction.	Compound AI3-70820-Ga did not produce a sensitization reaction under test conditions and is not expected to produce a sensitization reaction in man.
Ten positive control guinea pigs were sensitized over 3 weeks with DNCB. After 2 weeks rest, they were challenged with ID injections of DNCB.	Challenge dose of DNCB in positive control guinea pigs produced a marked sensitization reaction in 10 out of 10 guinea pigs.	DNCB produced a marked reaction, indicating the guinea pigs respond to sensitizing agents.

* A known skin senitizer

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5. CONCLUSION. Technical grade compound AI3-70820-Ga caused mild primary skin irritation and mild corneal irritation. It did not cause any photoirritation, did not produce any sensitization reaction, and did not prove to be an acute ingestion hazard.

6. RECOMMENDATION. Under the provisions of the Memorandum of Understanding (paragraph 1b), it is recommended that AI3-70820-Ga, USDA Proprietary Compound, be approved for further testing as a candidate insect repellent.

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APPENDIX

TOPICAL HAZARD EVALUATION PROGRAM
DEFINITIONS OF CATEGORIES OF COMPOUNDS BEING CONSIDERED FOR ACUTE SKIN APPLICATION

CATEGORY I - Compounds producing no primary irritation of the intact skin or no greater than mild primary irritation of the skin surrounding an abrasion. (INTERPRETATION: No restriction for acute application to the human skin.)

CATEGORY II - Compounds producing mild primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should be used only on human skin found by examination to have no abrasions or may be used as a clothing impregnant.)

CATEGORY III - Compounds producing moderate primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should not be used directly on the skin without a prophetic patch test having been conducted on humans to determine irritation potential to human skin. May be used without patch testing, with extreme caution, as clothing impregnants. Compound should be resubmitted in the form and at the intended use concentration so that its irritation potential can be reexamined using other test techniques on animals.)

CATEGORY IV - Compounds producing moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, producing necrosis, vesiculation, and/or eschars. (INTERPRETATION: Should be resubmitted for testing in the form and at the intended use concentration. Upon resubmission, its irritation potential will be reexamined using other test techniques on animals, prior to possible prophetic patch testing in humans, at concentrations which have been shown not to produce primary irritation in animals.)

CATEGORY V - Compounds impossible to classify because of staining of the skin or other masking effects owing to physical properties of the compound. (INTERPRETATION: Not suitable for use on humans.)

EYE CATEGORIES:

A. Compounds noninjurious to the eye. INTERPRETATION: Irritation of human eyes is not expected if the compound should accidentally get into the eyes, provided it is washed out as soon as possible.

B. Compounds producing mild injury to the cornea: INTERPRETATION: Should be used with caution around the eyes.

C. Compounds producing mild injury to the cornea and, in addition, some injury to the conjunctiva. INTERPRETATION: Should be used with caution around the eyes and mucosa.

D. Compounds producing moderate injury to the cornea. INTERPRETATION: Should be used with extreme caution around the eyes.

E. Compounds producing moderate injury to the cornea and, in addition, producing some injury to the conjunctiva. INTERPRETATION: Should be used with extreme caution around the eyes and mucosa.

F. Compounds producing severe injury to the cornea and to the conjunctiva. INTERPRETATION: Should be used with extreme caution. It is recommended that use be restricted to areas other than the face.